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ReedSmith

Toni-Junell Herbert
Direct Phone: 202.414.9203
Email: therbert@reedsmit.com



Reed Smith LLP
1301 K Street, N.W.
Suite 1100 – East Tower
Washington, D.C. 20005-3373
202.414.9200
Fax 202.414.9299

August 9, 2004

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PATENT TRADEMARK OFFICE

Commissioner Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Re: U.S. Patent Application
Serial No.: 10/026,911
Filed: December 27, 2001
For: Allergy Vaccines and Their Preparation
Inventor(s): Focke, et al.
Attorney Docket No.: 966927.00005

Sir:

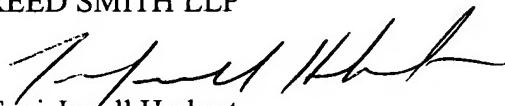
The following documents are forwarded herewith for appropriate action by the U.S. Patent and Trademark Office:

1. Transmittal Letter;
2. Petition for Extension of Time;
3. Response to Restriction Requirement;
4. Check in the amount of \$55.00; and
5. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier.

Respectfully submitted,

REED SMITH LLP


Toni-Junell Herbert
Reg. No. 34,348

Encl.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Focke et al.

Serial No.: 10/026,911

Filed: 12/27/01

For: Allergy Vaccines and Their Preparation

Art Unit: 1644

Examiner: Nolan, Patrick J.

Atty. Docket: 0273-0005
(966927.00005)

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Office Action dated June 7, 2004, requesting an election of claims in the above-referenced patent application, Applicants hereby provisionally elect to prosecute the claims of **Group 1 (Claims 1-9)**, with traverse.

This election is made without prejudice to or disclaimer of the other claims or inventions disclosed. Applicants reserve the right to file one or more divisional applications to the non-elected groups.

Traversing Restriction between Inventions I and II; and Inventions II and III

The Examiner has required a restriction under 35 U.S.C. §121 between Invention I, directed to claims 1-9 drawn to a pharmaceutical composition comprising a peptide exposed on an allergen, and Invention II, directed to claims 14-24 drawn to a method of preparing a composition by screening for solvent exposed amino acid residues by determining the hydrophilicity profile of the protein or by determining the three dimensional structure of the protein. The Examiner asserts that Inventions I and II are

related as apparatus and product made and that the composition can be made by screening for the solvent exposed amino acid residues by using epitope mapping of individual peptide fragments. The Examiner also asserts that Inventions I and II are related as product and process of use and that the product can be used in screening assays to determine which fragment elicit IgG versus IgE antibodies in test animals. Applicants respectfully disagree with the Examiner's requirement for restriction.

The Examiner has further required a restriction under 35 U.S.C. §121 between Invention II, directed to claims 14-24 drawn to a method of preparing a composition by screening for solvent exposed amino acid residues by determining the hydrophilicity profile of the protein or by determining the three dimensional structure of the protein, and Invention III, directed to claims 28-33 drawn to a method of treating with an allergenic peptide. The Examiner asserts that Inventions II and III are unrelated and "the methods are different endpoints and are patentably distinct." *See* Office action, p. 3. Applicants respectfully disagree with the Examiner's requirement for restriction.

The Examiner is required to make a *prima facie* showing that a restriction requirement is necessary. *See* M.P.E.P. §803. The Examiner must provide reasons and/or examples to support conclusions to support the restriction requirement. *See* M.P.E.P. §803. A restriction is proper only when two or more independent and distinct inventions have been claimed in one application. *See* 35 U.S.C. §121, 37 C.F.R. § 1.141. However, if the search and examination of an entire application can be made without serious burden, the examiner must examine that application on the merits, even though it includes claims to independent or distinct inventions. *See* M.P.E.P. §803.

Examining the Inventions Together Does Not Place Additional Burden on the Examiner

The Examiner has explained that Invention I is both an apparatus and a product. *See* Office action, p. 2. The Examiner has also explained that Invention II is both a product made and a process of use. *See* Office action, p. 2. Based upon the Examiner's

explanation of the Inventions, he asserts that the Inventions are distinct and therefore should be restricted. Applicants are unclear as to what the Examiner believes the Invention groups encompass. Further, the Examiner has only discussed restriction between Inventions I and II; and Inventions II and III. In light of the Examiner's failure to provide a *prima facie* showing of why the invention should be restricted, the Applicants respectfully request the restriction be withdrawn.

Where, as disclosed in the application, the several inventions claimed are related, and such related inventions are not patentably distinct as claimed, restriction under 35 U.S.C. §121 is never proper. *See* M.P.E.P. §806.02. If the Examiner classifies the inventions as distinct, the Examiner must also show by appropriate explanation that one of the criteria in M.P.E.P. §808.02(A-C) have been met. The Examiner must show that either (a) the inventions are classified separately, (b) the inventions have been classified together, but it can be shown that each subject has formed a separate subject for inventive effort, or (c) separate fields of search exist and it is necessary to search for one subject in a place where no pertinent art for the other subject exists. *See* M.P.E.P. §808.02. Where, however, the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among related inventions. *See* M.P.E.P. §808.02. Applicants respectfully believe the Examiner has not met the *prima facie* requirements under M.P.E.P. §808.

Where, as here, Invention I and Invention III are within the same class and subclass (class 514, subclass 12), and the search field is essentially the same for both, examining both sets of claims imparts no additional burden on the Examiner. Further, the claims of Invention III are dependent on the claims of Invention I. Since all three Inventions pertain to a pharmaceutical composition comprising a peptide sequence having a length of 8-50 amino acids, wherein at least three preferably consecutive amino acids of the peptide are identical to at least three solvent-exposed amino acids of an allergenic protein, examining the three sets of claims would not place a serious burden on the

Examiner. The elements of a peptide sequence having a length of 8 to 50 amino acids and being identical to at least three solvent-exposed amino acids of an allergenic protein, are integral and consistent throughout all of the claims and should not be examined separately.

Accordingly, the Applicant respectfully requests the Examiner withdraw the restriction requirement between the inventions.

Conclusion

For the reasons detailed above, reconsideration and withdrawal of the Requirement for Restriction, and consideration and allowance of all pending claims, are respectfully requested.

The elections made herein are without prejudice to or disclaimer of the other claims or inventions disclosed. Applicants reserve the right to file one or more divisional applications to the non-elected groups.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. §1.136(a), and any fees required therefor are hereby authorized to be charged to Deposit Account No. 50-0622.

Respectfully submitted,
REED SMITH, LLP


By: Toni-Junell Herbert
Reg. No. 34,348

Date: 8/9/04

1301 K Street, N.W.
Suite 1100 – East Tower
Washington, D.C. 20005
(202) 414-9200

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